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Section IX 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) Number is: _____

Date of Preparation	September 23, 2011
Sponsor	**Guangdong Biolight Meditech Co., Ltd [Reg #:3007305624]** Innovation First Road, Technology Innovation Coast Zhuhai, Guangdong, 519085, China Contact Person: Mr. Tianbao Li, Chief Engineer Tel: +86-756-3399963 | Fax: +86-756-3399989 | E-mail: li_tb@blt.com.cn
Submission Correspondent	Ms. Diana Hong / Mr. Lee Fu Mid-Link Consulting Co., Ltd P.O. BOX 237-023, Shanghai, 200237, China
Proposed Device	**Patient Monitor, M8500** Modification to: M9000 Patient Monitor as cleared in K100046 21 CFR 870.1025 | MHX | Class II
Intended Use	Patient Monitors, M8500, are intended to be used for monitoring, displaying, reviewing, storing and alarming of multiple physiological parameters including ECG, Heart Rate (HR), Respiration Rate (RESP), Pulse Oxygen Saturation (SpO2), Pulse Rate (PR), Non-invasive Blood Pressure (NIBP), carbon dioxide (CO2), and Temperature (TEMP) of adult, pediatric and neonatal patient. The monitors are to be used in healthcare facilities by clinical physicians or appropriate medical staff under the direction of physicians. They are not intended for helicopter transport or hospital ambulance.
Device Description	The proposed devices are intended to be used for monitoring, displaying, reviewing, storing and alarming of multiple physiological parameters including ECG, Heart Rate (HR), Respiration Rate (RESP), Pulse Oxygen Saturation (SpO2), Pulse Rate (PR), Non-invasive Blood Pressure (NIBP), carbon dioxide (CO2), and Temperature (TEMP) of adult, pediatric and neonatal patient. They have the alarming function with audio and visual alarming, which may raise

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	the user attention of system error and exceeding the pre-set limit of physiological parameter, and data storage function, which can replay the data and alarming event. The device is driven by AC or DC power supply.
Test Summary	Per the risk management during the design change control, the verification tests performed demonstrated that risks of each hazard are reduced to acceptable region.
Conclusion	The proposed devices are Substantially Equiavlent (SE) to the predicate device, M9000 Patient Monitor as cleared in K100046, with respect of effectiveness and safety.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 24 2011

Guangdong Biolight Meditech Co., Ltd.
c/o Ms. Diana Hong
General Manager
Mid-Link Consulting Co., Ltd.
P.O. Box 237-023
Shanghai 200237
CHINA

Re: K112803
Trade/Device Name: Patient Monitor, Model M8500
Regulatory Number: 21 CFR 870.1025
Regulation Name: Patient Physiological Monitor (with arrhythmia detection or alarms)
Regulatory Class: II (two)
Product Code: 74 MHX
Dated: September 15, 2011
Received: September 17, 2011

Dear Ms. Hong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

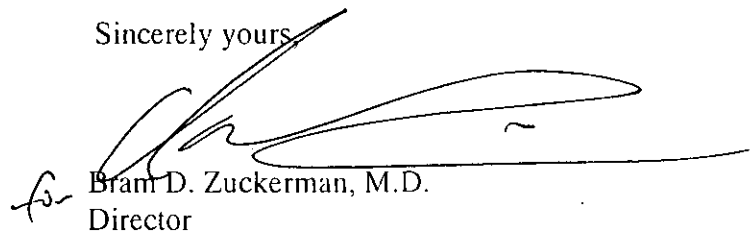
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Section III Indication for Use Form

510(k) NUMBER (if known):

DEVICE NAME: Patient Monitor

INDICATION FOR USE:

Patient Monitors, M8500, are intended to be used for monitoring, displaying, reviewing, storing and alarming of multiple physiological parameters including ECG, Heart Rate (HR), Respiration Rate (RESP), Pulse Oxygen Saturation (SpO2), Pulse Rate (PR), Non-invasive Blood Pressure (NIBP), carbon dioxide (CO2), and Temperature (TEMP) of adult, pediatric and neonatal patient.

The monitors are to be used in healthcare facilities by clinical physicians or appropriate medical staff under the direction of physicians. They are not intended for helicopter transport or hospital ambulance.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

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